

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference C1-A0401P	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2005/005824	International filing date (day/month/year) 29.03.2005	Priority date (day/month/year) 29.03.2004
International Patent Classification (IPC) or national classification and IPC . A61K48/00, A61K31/7088, A61P35/00, A61P35/02		
Applicant SUGIYAMA, Haruo		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/IP	Authorized officer
Facsimile No.	Telephone No.

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Box No. 1 Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 8-20

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8-20

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV

Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:

The invention set forth in claim 1 pertains to cell proliferation inhibitors that include any one of the belowmentioned components (a) to (c) as an active component:

(a) a double-stranded RNA, which includes a strand of RNA that is complimentary to the transcription product of the WT1 gene and a strand RNA that is complimentary to said strand of RNA;

(b) a DNA which encodes the double-stranded RNA described in (a); or

(c) a vector having the DNA described in (b) inserted therein.

[Refer to the Supplemental Box]

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-7

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-7	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
<Citations>			
<p>Document 1: Yoji MURATA et al., "The Wilms' tumor suppressor gene WT1 induces G1 arrest and apoptosis in myeloblastic leukemia M1 cells," FEBS Letters, 1997, Vol. 409, No. 1, pages 41 to 45</p> <p>Document 2: K. INOUE et al., "Wilms' tumor gene (WT1) competes with differentiation-inducing signal in hematopoietic progenitor cells," Blood, 1998, Vol. 91, No. 8, pages 2969 to 2976</p> <p>Document 3: Y. OJI et al., "Expression of the Wilms' tumor gene WT1 in solid tumors and its involvement in tumor cell growth," Japanese Journal of Cancer Research, 1999, Vol. 90, pages 194 to 204</p> <p>Document 4: Jamie A. DAVIES et al., "Development of an siRNA-based method for repressing specific genes in renal organ culture and its use to show that the WT1 tumor suppressor is required for nephron differentiation," Human Molecular Genetics, 15 January 2004, Vol.</p>			

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

13, No. 2, pages 235 to 246

<Explanations>

The inventions set forth in claims 1 to 7 do not involve an inventive step in the light of documents 1 to 4 cited in the international search report.

Documents 1 to 3 indicate that the WT1 gene performs an oncogene-like function, and also indicate that it is possible to suppress the proliferation of leukemia cells by suppressing the function of the WT1 gene.

Meanwhile, document 4 presents siRNA that targets the WT1 gene, and goes on to indicate that said siRNA suppresses the function of the WT1 gene.

Such being the case, it is considered to be easy for a person skilled in the art to confirm whether siRNA that targets the WT1 gene actually exhibits a antiproliferative action, or to configure the inventions set forth in claims 1 to 7 of the present application by selecting an appropriate target site upon the WT1 gene.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☒ contained in the international application as filed
 - ☐ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX IV.3

However, siRNAs that target the WT1 gene are well known (for example, refer to the document [Jamie A. DAVIES et al., "Development of an siRNA-based method for repressing specific genes in renal organ culture and its use to show that the WT1 tumor suppressor is required for nephron differentiation," Human Molecular Genetics, 15 January 2004, Vol. 13, No. 2, pages 235 to 246]), and thus there is no common feature that can be considered to be a special technical feature, in the meaning of the second sentence of PCT Rule 13.2, among the invention set forth in claims 1 to 7, the invention set forth in claims 8 to 12, the invention set forth in claims 13 to 14, the invention set forth in 15 to 16, the invention set forth in claims 17 to 18 and the invention set forth in 19 to 20. As a result, it is impossible to find a technical relationship, in the meaning of PCT Rule 13, among these different inventions.

Such being the case, the inventions in question do not share a technical relationship that involves one or more of the same or corresponding special technical features; consequently, said inventions cannot be considered to be linked so as to form a single general inventive concept.